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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,200	01/23/2001	Ernst Peter Rieber	028622/0103	1983

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,200	RIEBER, ERNST PETER	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-11,16,17,30,41-43,45 and 58-63* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-6,8-11,16,17,41-43,45 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendments and remarks, filed 6/15/04, are acknowledged. In view of Applicant's amendments and remarks all objections to the specification have been withdrawn. As set forth below, some of the previous rejections under 35 U.S.C. 112, second paragraph have been withdrawn. Additionally, Applicant's declaration regarding the deposit of the claimed hybridoma has obviated the previous rejection under 35 U.S.C. 112, first paragraph, as it regarded the lack of enablement. Finally, Applicant's amendments have obviated the previous rejection under U.S.C. 102(e) as being clearly anticipated by U.S. Patent No. 5,766,570.

2. In view of the instant amendment, Claims 41-43 and 45 now read on the elected invention. Accordingly, Claims 1-6, 8-11, 16-17, 41-43, 45, and newly added Claims 58-63 read on the elected invention and are being acted upon.

3. Claim 30 stands withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Applicant's request for rejoinder is noted.

4. The Abstract submitted 6/15/04 has been found acceptable.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6, 8-11, 16-17, 41-43, 45, and newly added Claims 58-63 stand/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) In Claims 1 and 17, the recitation of the phrase, "does not react with", remains vague and indefinite.

B) In Claim 2, the recitation of "wherein the DCs comprise a DC population of a maturational stage between immature and mature DCs", is vague and indefinite as it is unclear what "comprise" means in the instant context.

C) In Claim 5, the recitation of "DCS of a restricted size and granularity", remains vague and indefinite as these comprise terms for which the precise limitations cannot be known.

D) Rejection withdrawn in light of Applicant's amendments.

E) Rejection withdrawn in light of Applicant's amendment.

F) Rejection withdrawn in light of Applicant's amendment.

Applicant's arguments, filed 6/15/04, have been fully considered but they are not persuasive.

Regarding A), Applicant argues that the term is disclosed in a newly submitted reference (Roitt et al.). A review of the reference discloses antibody binding but does not disclose a definition for antibody "reacting".

Regarding B), Applicant argues that the amending of "represent" to "comprises" obviates the rejection. It is the Examiner's position that the amendment seems to create a new ground for rejection by not further limiting the subject matter of the claim. In reciting "comprising", the claim encompasses DCs of a maturational stage between immature and mature, as well as DCs of any other maturational stage.

Regarding C), Applicant argues that a person skilled in the art would know how size and granularity would be determined and cites the newly submitted reference (Roitt et al.) again, as well as a German reference that has not been considered. It remains the Examiner's position that the metes and bounds of the claim cannot be determined. The Roitt et al. reference is silent regarding the determination of cell size and granularity, and as set forth previously, the German reference has not been considered. Accordingly, Applicant's arguments comprise only an attorney's assertions which have not been found convincing. It might also be noted that the Examiner might be considered one of skill in the art in view of the Examiner's peer-reviewed publications on the subject of granules in cytotoxic cells.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6, 8-9, and 16-17 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

A set forth previously, there is insufficient written description to show that Applicant was in possession of the "an antibody fragment of derivative thereof", recited in the claims.

Applicant's arguments, filed 6/15/04, have been fully considered but they are not persuasive. Applicant argues that "Applicants have amended claims 6, 16 and 17 to specifically recite that the fragments or derivatives of the antibody are capable of binding to the epitope (claims 6 and 17) or to the DCs (claim 16). Applicants submit that the antibody and the hybridoma that produces the antibody are provided, and thus fragments of such antibodies can be prepared and tested for the capability of binding to the same epitope as the complete antibody binds".

First note that the newly added functional requirement has not been added to the claims in such a way so as to encompass the claimed "derivatives". Regardless, Applicant's argument would be more appropriate for a rejection for lack of enablement. The instant rejection is for lack of adequate written description, i.e., the specification fails to adequately disclose the essentially unlimited genuses of antibody fragments and derivatives. Applicant's assertion that the claimed fragments can be identified cannot be considered an adequate written description.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 6, 10, 16-17, and newly amended Claims 41-43, and 45, stand/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 93/04187 (of record).

WO 93/04187 teaches a monoclonal antibody composition which reacts with human DCs and not other PBMCs, a continuous stable cell line (a hybridoma), and a method for preparing said antibody (see particularly pages 2, 5, 20, and 26). The reference also teaches a pharmaceutical composition (see particularly page 13), a diagnostic composition (see particularly page 13), and an invention that could be considered a "kit", i.e., an antibody and ligands (see particularly page 14).

Applicant's arguments, filed 6/15/04, have been fully considered but they are not persuasive. Applicant argues, "applicants submit that the MCR [sic] OX-2 antibody (see the attached abstract of a publication, J. Exp. Med. (1992), which

discloses that this antibody has specificity for DCs in rats whereas the antibody of the present invention, M-DC8, is specific for human DCs".

Applicant is advised that the reference teaches a humanized version of MRC OX-62 for use in human therapy. As the antibody is used in human therapy, it is clear that the humanized antibody binds human DCs.

11. The following are new grounds for rejection necessitated by Applicant's amendment.

12. Claims 1-6, 8-11, 16-17, 41-43, 45, and newly added Claims 58-63, are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) the recitation of the generic antibody of the claims which binds "human DCs displaying one or more surface markers of both immature and mature human DCs" (Claims 1 and 17).

B) the generic method comprising the steps of Claim 1 and the limitations of Claims 58-63.

Regarding A), Applicant indicates that support for the new limitation can be found at page 6, Table 1, and Figure 8. A review of the specification shows that the DCs bound by the antibody of the claims display specific combinations of markers and not the mix-and-match combinations that would be encompassed by the claims. For example, Figure 8 discloses that the DCs bound by the antibody of the claims would be $CD33^{dim}$, $HLA\text{-}DR^{dim}$ $CD11c^{+}$, etc., not any and all combinations of "surface markers" as claimed.

Regarding B), Applicant indicates that support for the new claims can be found in the various examples. It is noted, however, that the examples disclose only specific antibodies such as M-DC8. A disclosure of the properties of a specific antibody are insufficient support for said properties being applied to the generic antibodies of the claims.

13. No claim is allowed.

14. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

16. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

8/30/04

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